

DEPT OF
ATTORNEY GENERAL

FEB 25 2008

HEALTH CARE FRAUD DIVISION

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release ("Settlement Agreement") is entered into by the State of Michigan (hereinafter "the State") and Merck & Co., Inc. ("Merck"), through their authorized representatives, (hereinafter referred to collectively as "the Parties").

II. PREAMBLE

A. WHEREAS, Merck is a corporation organized under the laws of the State of New Jersey. At all relevant times, Merck manufactured, marketed and sold branded pharmaceutical products in all of the United States and the District of Columbia, including various formulations of the drug Pepcid (generic name famotidine).

B. WHEREAS, this Settlement Agreement addresses the civil claims of the State against Merck for the conduct described in the First Amended Consolidated Complaint in the case United States, et al., ex rel. William St. John LaCorte v. Merck & Co., Inc., Civil No 99-3907, Eastern District of Louisiana UNDER SEAL, (the "U.S. Civil Action") and the conduct alleged in Preamble Paragraph F below.

C. WHEREAS, at all material times, Merck participated in the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, which is part of federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the "Medicaid Program"). As a participant in the Medicaid Drug Rebate Program, Merck entered into a Rebate Agreement with the Health Care Financing Administration ("HCFA"), currently known as the Centers for Medicare and Medicaid Services ("CMS"), and Merck's drug products, including Pepcid, were covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42

U.S.C. §§ 1396a(10)(A); 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Drug Rebate Program and rebate agreement with HCFA, Merck generally agreed: (i) to report quarterly to HCFA its Average Manufacturer Price (AMP) and, for single source and innovator multiple source drugs, Best Price for its drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the average manufacturer price and best price, or a minimum rebate percentage of the average manufacturer price, as further defined in 42 U.S.C. § 1396r-8(c)(1).

D. WHEREAS, Merck has entered into or will be entering into a separate settlement agreement (hereinafter referred to as the "Federal Settlement Agreement") with the United States which will be receiving settlement funds from Merck pursuant to that Federal Settlement Agreement.

E. WHEREAS, Merck submitted or caused to be submitted certain reported prices for certain of its pharmaceutical products to CMS pursuant to the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8.

F. WHEREAS, the State contends that it has certain civil and administrative monetary claims against Merck for engaging in the following alleged conduct:

i. The State alleges that for the third reporting quarter of 1996 and continuing through the second reporting quarter of 2001, Merck knowingly misreported Best Prices to HCFA and underpaid rebates owed under the Medicaid Drug Rebate Program for the following formulations of Pepcid: Pepcid Tablet 20mg (NDC 00006-0963); Pepcid Tablet 40mg (NDC 00006-0964); Pepcid Oral Suspension (NDC 00006-3538); Pepcid RPD 20mg (NDC 00006-

3553); Pepcid RFD 40mg (NDC 00006-3554); Pepcid IV 20mg (NDC 00006-3539); Pepcid IV 20mg/2ml (NDC 00006-3541); and Pepcid Injection Premixed (NDC 00006-3537) (collectively Pepcid Formulations).

More specifically, the State contends that Merck's reported Best Prices on the Pepcid Formulations during the time period identified above failed to account accurately for certain tiered discounts, including so-called "nominal prices" for Pepcid Tablets, offered to hospitals and Group Purchasing Organizations (GPOs) under a pricing arrangement known as the FLEX NP (Nominal Pricing) Program for Pepcid. Additionally, the State contends that under the FLEX NP Program, Merck offered tiered discounts of up to 92% off the AMP for Pepcid Tablets, and lesser discounts on other formulations of Pepcid, based upon a hospital's achievement of certain market share requirements for purchase of multiple formulations of Pepcid. The State also contends that the FLEX NP Program discounts were greater than discounts received by hospitals that did not participate in the FLEX NP Program. Accordingly, the State contends that transactions under the FLEX NP Program constituted "bundled sales" pursuant to the rebate agreement with HCFA and, as such, discounts relating to these sales should have been reallocated among all products in calculating Best Price. The State contends that such a reallocation would have resulted in reportable Best Prices on the Pepcid Formulations that were lower than the Best Prices Merck reported to HCFA for the period beginning in the third reporting quarter of 1996 through the second reporting quarter of 2001. Finally, the State contends that Merck offered the discounts under the FLEX NP Program to induce improperly hospitals and GPOs to purchase or recommend the purchase of Pepcid Formulations for inpatient use, and to drive utilization of Pepcid outside the hospital based upon patients' continued usage of the drug following discharge.

G. WHEREAS, Merck's conduct described in the U.S. Civil Action and the conduct set forth in Preamble Paragraph F is hereafter referred to as the "Covered Conduct."

H. WHEREAS, this Settlement Agreement is made in compromise of disputed claims. This Settlement Agreement is neither an admission of liability by Merck, nor a concession by the State that its claims are not well founded. Merck expressly denies the allegations of the United States, the State and the Relator as set forth herein and in the U.S. Civil Action and denies that it has engaged in any wrongful conduct in connection with the Covered Conduct. Neither this Settlement Agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of the settlement, is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting upon the merits of the dispute by Merck.

I. WHEREAS, to avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

1 Merck agrees to pay to the United States and the States (defined for the purposes of this agreement as the District of Columbia and every State (except Arizona)) (hereinafter collectively referred to as "States"), collectively, the total amount of \$250,000,000.00 in principle, plus interest as described herein (the "Settlement Amount"). The Settlement Amount is to be paid to the United States and the States as follows:

a. Merck and the United States agree that the principal sum of \$137,500,000.00 plus interest represents the Federal share (the "Federal Settlement Amount").

Merck agrees to pay the Federal Settlement Amount, in accordance with the terms of the Federal Settlement Agreement.

b. Merck and the States agree that the sum of \$112,500,000.00, plus interest accrued at 5.22% per annum beginning October 28, 2007 and continuing through the date of payment, represents the States' share (the "State Settlement Amount") under the terms and conditions agreed upon by Merck and the States under separate State Settlement Agreements (the "State Settlement Agreements"). The State Settlement Amount shall be paid by electronic funds transfer to an account designated by the National Association of Medicaid Fraud Control Units ("NAMFCU") negotiating team ("NAMFCU Team"). Merck agrees to make this electronic funds transfer no later than five business days after the Federal Settlement Agreement's Effective Date.

c. The total portion of the Settlement Amount paid by Merck in settlement for the Covered Conduct to the State of Michigan is \$3,991,619, consisting of a portion paid to the State of Michigan under this agreement and another portion paid to the federal government as part of the Federal Settlement Agreement. The individual portion of the State Settlement Amount allocable to the State of Michigan under this agreement is the sum of \$1,683,890 ("Individual State Settlement Amount").

2. Subject to the exceptions in Paragraph 3 (reservation paragraph), below, in consideration of the obligations of Merck in this Settlement Agreement, conditioned upon Merck's full payment of the Settlement Amount, the State (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Merck, together with its current and former parent corporations, each of its direct and indirect subsidiaries, both current and former, divisions, brother and sister corporations, and the predecessors, successors and assigns of any of them

(collectively "Merck Released Entities"), as well as the interest of the Merck Released Entities in any joint venture, from any civil or administrative monetary claims for the Covered Conduct arising from Merck's participation in the State Medicaid Program. The Parties agree that the interest of any non-Merck Released Entity in any joint venture is not within the scope of this release.

3. Notwithstanding any term of this Settlement Agreement, the State specifically does not release any person or entity from any of the following claims or liabilities:

- a. Any civil, criminal or administrative liability arising under the State's revenue codes;
- b. Any criminal liability;
- c. Except as explicitly stated in this Settlement Agreement, any administrative liability including mandatory exclusion from the State's Medicaid program;
- d. Any liability to the State (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon such obligations as are created by the Settlement Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for personal injury or property damage from the Covered Conduct;
- h. Any liability based on a failure to deliver items or services due;
- i. Any civil or administrative liability that Merck has or may have under any state statute, regulation, or rule not expressly covered by the release in Paragraph 2, including, but not

limited to any civil liability relating to State claims for anti trust violations, claims involving unfair and/or deceptive acts and practices under the State's consumer protection laws which any person or entity has or may have to individual consumers or state program payors other than the Medicaid program; and

j. Any claims related to the improper inflation of Average Wholesale Prices and Wholesale Acquisition Costs used for Medicaid reimbursement; provided, however, that Merck and any Merck Released Entity does not waive any rights or defenses that they may have with respect to liability or damages in connection with such claims.

4. In consideration of the obligations of Merck in this Settlement Agreement and the Corporate Integrity Agreement ("CIA") entered into between the Office of the Inspector General of the United States Department of Health and Human Services ("HHS-OIG") and Merck and incorporated herein by reference, conditioned upon Merck's full payment of the Federal and State Settlement Amounts, the State agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid Program, except as reserved in Paragraph 3, for the Covered Conduct. Nothing in this Agreement precludes the State from taking action against Merck in the event that Merck is excluded by the federal government, or for conduct and practices other than the Covered Conduct. The State does not have the authority to release Merck from any claims or actions which may be asserted by private payers or insurers, including those that are paid by a State's Medicaid Program on a capitated basis.

5. Merck waives and shall not assert any defenses Merck may have to any criminal prosecution or administrative action for the Covered Conduct arising from Merck's participation in the State Medicaid Program which defense may be based in whole or in part on a contention

that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Settlement Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Settlement Agreement constitutes an agreement by the State concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code or the State revenue codes.

6. The Merck Released Entities fully and finally release the State, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that the Merck Released Entities have asserted or could have asserted as of the date of this Settlement Agreement against the State, its agencies, employees, servants, and agents, for the Covered Conduct arising from Merck's participation in the State Medicaid Program and the investigation thereof.

7. The Settlement Amount that Merck must pay pursuant to Paragraph 1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State's Medicaid Program or any other state payer, related to the Covered Conduct; and, if applicable, Merck agrees not to resubmit to the State's Medicaid Program or any other state payer, any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal or cause the appeal of any such denials of claims.

8. Upon receipt of reasonable notice, and consistent with the rights and privileges of Merck and all individuals referenced in this paragraph, Merck shall make reasonable efforts to encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, with any State investigation related to the Covered Conduct, and shall use its best efforts to make available, and encourage the cooperation of former directors, officers, and employees for

interviews and testimony concerning the Covered Conduct, and, upon receipt of reasonable notice, Merck agrees to furnish to the State complete and unredacted copies of all non-privileged documents and records in its possession, custody, or control concerning the Covered Conduct. Cooperation shall not be construed to include the waiver of any attorney client, work product, or other privileges.

9. Merck waives and shall not seek payment for any of the health care billings covered by this Settlement Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the claims defined as the Covered Conduct.

10. Merck warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States and the States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Merck, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Merck was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1)(A).

11. Within two business days of the Effective Date of this Settlement Agreement, the State agrees that it will dismiss with prejudice the U.S. Civil Action pending in the United States

District Court for the Eastern District of Louisiana (if applicable), as well as any other federal and/or state false claims act actions filed in any court or brought on behalf of the State insofar as the actions relate to the Covered Conduct.

12. Except as expressly provided to the contrary in this Settlement Agreement, each Party to this Settlement Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Settlement Agreement.

13. This Settlement Agreement is intended to be for the benefit of the Parties only. Other than as set forth in this Settlement Agreement, the parties do not release any claims against any other person or entity.

14. In addition to all other payments and responsibilities under this Settlement Agreement, Merck agrees to pay all reasonable travel costs and expenses of the NAMFCU Negotiating Team. Merck will pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units after the States execute this agreement or as otherwise agreed by the parties.

15. This Settlement Agreement is governed by the laws of the State, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA.

16. The individuals signing this Settlement Agreement on behalf of Merck represent and warrant that they are authorized by the Board of Directors to execute this Settlement Agreement. The undersigned State signatories represent that they are signing this Settlement Agreement in their official capacities and they are authorized to execute this Settlement Agreement on behalf of the State through their respective agencies and departments.

17. As used in this Settlement Agreement, the "Effective Date" shall mean the date of the signature of the last signatory to the Settlement Agreement.

18. Merck represents that this Settlement Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

19. This Settlement Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

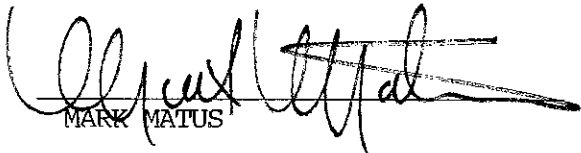
20. This Settlement Agreement and the CIA constitute the complete agreement between the Parties. This Settlement Agreement shall not be amended except by written consent of the Parties, except that only Merck and OIG-HHS must agree in writing to modification of the CIA, without the consent of any other party to this Settlement Agreement.

21. This Settlement Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Settlement Agreement.

THE STATE OF MICHIGAN

DATED: 1/17/2008

The State of Michigan
Office of the Attorney General
Medicaid Fraud Control Unit

BY: 
MARK MATUS

Title: Assistant Attorney General
Dept of Attorney General
Health Care Fraud Division
2860 Eyde Parkway
East Lansing, MI 48909
(517) 241-6500

DATED: 1/10/2008

The State of Michigan
Medicaid Program

BY: 

Title: Director, Bureau of Medicaid
Financial Mgmt. & Administrative
Services


MERCK & CO., INC. - DEFENDANT

DATED: 02/05/08

BY: 

BRUCE KUHLIK
Executive Vice-President & General Counsel
Merck & Co., Inc.

DATED: 02/05/08

BY: 

LISA C. DYKSTRA
Morgan, Lewis & Bockius, LLP
Counsel for Merck & Co., Inc.

DATED: _____

BY: _____

ERIC H. HOLDER, JR.
Covington & Burling LLP
Counsel for Merck & Co., Inc.

Merck & Co., Inc.

DATED: _____

BY: _____

BRUCE KUHLIK
Executive Vice-President & General Counsel
Merck & Co., Inc.


DATED: _____

BY: _____

LISA C. DYKSTRA
Morgan, Lewis & Bockius, LLP
Counsel for Merck

DATED: 02/05/08

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ERIC H. HOLDER, JR.
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